

REMARKS

Reconsideration of the present application is respectfully requested in view of the above amendments and the following remarks. By the present amendment, claim 38 is canceled, and claims 1-3, 20-23, 32, 80, and 96 are amended to more specifically focus on certain aspects of the present invention. Support for these claims is provided in the application as filed, and this amendment does not introduce new matter. In addition, it should be noted that the amendment is made without acquiescence to any of the rejections and without prejudice to the prosecution of claims directed to any subject matter modified or removed by the amendments in one or more related continuing applications.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-3, 20-23, 32, 37, 38, 80 and 96 stand rejected as allegedly being indefinite. Specifically, the Examiner alleges that claims 1, 21, 32, 80, and 96, and claims 2, 3, 20, 22, 23, 37, and 38 dependent therefrom, are indefinite in their recitation of “other tissue components” and “cells therein,” claims 2 and 22 are indefinite in their recitation of “fibroblast-like cells,” claims 3 and 23 are indefinite in their recitation of “extracellular matrix polypeptides or fragments thereof,” claims 20, 22, and 23 are indefinite in their recitation of “tail head region,” and claim 80 is indefinite in its recitation of “a series of screens.”

Without acquiescence to this basis of rejection, the claims have been amended to provide additional clarity.

Claims 1, 21, 32, 80, and 96 have been amended to remove the phrase “other tissue components” and instead recite that the cells are separated from lipids. Support for this amendment is provided on page 13, lines 13-14, of the instant application as filed. Claims 1, 21, 32, 80, and 96 have also been amended to replace the phrase “cells therein” with the phrase “the cells therein” (emphasis added), to clarify that this step refers generically to any cells in the adipose tissue as opposed to a particular subpopulation of cells. Claims 1 and 38 are amended to clarify that the other purified cells were originally present in the adipose tissue.

Claims 2 and 22 are amended to remove reference to fibroblast-like cells, thus obviating this basis of rejection.

Claims 3 and 23 are amended to remove reference to fragments, thus obviating this basis of rejection.

Claims 20 and 21 are amended to recite that the patient is an animal having a tail. Support for this amendment is implicitly provided throughout the instant specification. For example, the specification describes that patients may be humans or other animals and refers indirectly to animals having tails on page 9, lines 21-23. With respect to the phrase “tailhead region,” Applicants submit that this term would be readily understood by one of skill in the art of veterinary medicine, particularly in view of the definition provided on page 9, lines 21-24, of the instant application. Accordingly, Applicants respectfully submit that this term is, indeed, definite.

Claim 80 is amended to replace the phrase “series of screens” with the phrase “a device comprising an array of screens,” thus clarifying that the screens are physical screens as opposed to screening methods. Support for this amendment is provided on page 10, lines 21-22.

In view of the above amendments and remarks, Applicants respectfully submit that the claims of the instant application satisfy the requirements of 35 U.S.C. § 112, second paragraph, and request that the Examiner reconsider and withdraw this basis for rejection.

Rejection Under 35 U.S.C. § 102

Claims 1-3, 20-23, 32, 37, 38, and 96 stand rejected as allegedly being anticipated by Zuk *et al.* (2001, *Tissue Engineering*, 211-228), on the basis that these claims read on embodiments in which the term “separate stem cells therein” is interpreted as “separate at least some cells therein,” and in which “other tissue components” may include mature adipocytes.

Applicants respectfully traverse this basis of rejection and submit that the presently claimed methods are clearly novel over the methods described by Zuk *et al.*, since Zuk *et al.* fail to describe each element of the presently claimed method, as required to establish a *prima facie* case of anticipation under Section 102. *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440 (Fed. Cir. 1984). Applicants note that claims 32, 80 and 96 are amended, without acquiescence to any basis of rejection, to recite that the claimed method does not include purifying or isolating stem cells from other cells. Therefore, claims 1-3, 20, 32, 37, 80, and 96 explicitly recite the element that the claimed method does not include isolating stem cells from

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other purified or isolated cells. In sharp contrast, according to the method described in Zuk *et al.*, cells isolated from adipose tissue are treated with ammonium chloride to lyse red blood cells (page 213, lines 1-2). Accordingly, this method includes the step of isolating the stem cells from other purified or isolated cells (*i.e.*, red blood cells). Thus, Zuk *et al.* fails to teach each element of the recited method, thus, cannot anticipate the instant claims.

Furthermore, with respect to claims 21-23, these claims recite that adipose tissue is obtained from the tail head region of an animal having a tail. Zuk *et al.* fails to teach this element of the recited method and, therefore, cannot anticipate the instant claims.

In view of the above amendments and remarks, Applicants respectfully request that this basis of rejection be reconsidered and withdrawn.

Rejection Under 35 U.S.C. § 103

Claim 80 stands rejected as allegedly being unpatentable over Zuk *et al.*, on the basis that duplicating a method step is *prima facie* obvious.

Applicants respectfully traverse this basis of rejection and submit that the instant claim is not rendered obvious by Zuk *et al.* It appears that this rejection is premised on the Examiner's understanding that the phrase "a series of screens" could be interpreted to mean repeating screening methods. Without acquiescence to any basis of rejection, claim 80 has been amended to replace this phrase with "a device comprising an array of screens." Zuk *et al.* do not describe contacting collagen-based tissue with a device comprising an array of screens. In addition, as described above with respect to the rejection under Section 102, Zuk *et al.* also fail to teach a method that does not include isolating stem cells from other purified or isolated cells. Therefore, Zuk *et al.* clearly fail to teach each element of claim 80 and, thus, cannot render it obvious. *KSR v. Teleflex, Inc.*, No 04-1350 at 4, 14 (U.S. Apr. 30, 2007).

Furthermore, Applicants submit that the presently claimed methods offer surprising and unexpected advantages over prior art methods, including those described in Zuk *et al.* As described in the instant application, the methods of the present invention result in a cell population having increased efficacy and stability as compared to stem cells purified using previous methods, which typically include one or more additional steps of isolating stem cells from other cells present in a tissue source and/or culturing or differentiating the isolated stem

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cells prior to administration to a patient (page 7, lines 22-28). In addition, as described in the accompanying Declaration of Jeffrey Catania, a direct comparison of the presently claimed method, which does not include the step of lysing red blood cells, to the method described in Zuk *et al.*, which includes the step of lysing blood cells, clearly demonstrates that the presently claimed method results in a significantly increased number of nucleated cells, *i.e.*, approximately 20% more nucleated cells. This, of course, is tremendously advantageous, considering the limited tissue source for obtaining such cells, and the desire to administer a large number of stem cells for therapeutic purposes. In addition, the reduction in nucleated cell number after treatment with ammonium chloride is surprising, since this step is included to remove red blood cells, which are enucleated. Applicants submit that these surprising and unexpected advantages provide additional evidence of the non-obviousness of the presently claimed methods.

In view of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of this basis of rejection.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all of the claims in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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Enclosure:

Declaration of Jeffrey Catania

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